## Remarks

The Office Action mailed 16 February 2005 has been received and reviewed. Claims 1, 34, 40-43, 54, 57, and 58 having been amended, the pending claims are claims 1-43 and 54-63. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the amendments can be found throughout the specification and in the originally filed claims. For example, support for the amendment to claim 43 is at page 9, line 6. Support for the amendment to claim 42 is at page 7, line 10.

### Obviousness-Type Double Patenting Rejection

Claims 1-21, 25-30, 37-39, 41-43, and 54-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 16-25, 27, 29-44, and 47-60 of U.S. Patent No. 10/922,262 or claims 1-7, 16-25, 27, 29-44, and 47-59 of U.S. Patent No. 6,838,078 in view of Kross et al. (U.S. Patent No. 5,618,841), Brink et al. (U.S. Patent No. 5,173,291), and Beach (U.S. Patent No. 3,380,923) in further view of Talwalker et al (U.S. Patent No. 5,462,714) and Richter et al. (U.S. Patent No. 6,379,685). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

### The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-21, 25-30, 37-39, 41-43, and 54-63 under 35 U.S.C. §103(a) as being unpatentable over Kross (U.S. Patent No. 5,618,841) in view of Brink et al. (U.S. Patent No. 5,173,291) and Beach (U.S. Patent No. 3,380,923) in further view of Talwalker et al. (U.S. Patent No. 5,462,714) and Richter et al. (U.S. Patent No. 6,379,685). This rejection is respectfully traversed.

> "When applying 35 U.S.C. § 103, the following tenets of patent law must be adhered to:
> (A) The claimed invention must be considered as a whole;
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
(D) Reasonable expectation of success is the standard with which obviousness is determined." M.P.E.P. § 2141 (citations omitted, emphasis added).

Applicants respectfully submit that the combination of five documents, Kross et al. in view of Brink et al. and Beach in further view of Talwalker et al and Richter et al., in an obviousness rejection can only occur by the impermissible use of hindsight reasoning. Furthermore, Applicants respectfully submit that the Examiner is picking and choosing from each of these documents, without considering them in their entirety.

In order to establish a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 at 93 ("Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, . . . was a legally improper way to simplify the difficult determination of obviousness."). One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 933 F2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). Even without considering the merits of the rejection or the specifics of each document, it is difficult to imagine how hindsight is not being used when a combination of five documents are in an obviousness rejection.

Further, both the suggestion for combining the teachings of the prior art to make the invention and the reasonable likelihood of its success must be founded in the prior art and not in the teachings of Applicants' disclosure. In re Dow Chem., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Here, the cited documents neither suggest the combination of its teachings nor suggests the reasonable likelihood that such a combination would result in the claimed invention. Applicants respectfully submit that there is simply no teaching, suggestion, or incentive indicated in any of the five cited documents that provides a motivation to combine their teachings to provide the claimed composition.

Also, at page 5 of the Office Action, the Examiner appears to have alleged that Applicants have not presented arguments directed to the combination of the cited documents by stating that "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." Applicants' Representatives disagree.

First of all, the deficiencies in the individual documents have been discussed and appropriately evidence, for example, the following: that the rejections were created by "picking and choosing" from each of the documents; that the documents have not been considered as a whole or the invention as a whole; and that hindsight reconstruction has been used. Applicants' submit that there is no motivation to combine such documents – particularly when it takes five documents to make a nonobviousness rejection.

Second, not only have Applicants provided arguments as to why the combination of documents used by the Examiner is inappropriate, but they have presented declaratory evidence of this. For example, the Declaration of Matthew Scholz submitted with the last response presented evidence as to why one of skill in the art would not combine Kross with Brink et al. This evidence was in the form of an example that was carried out after discussion with the Examiner about the appropriateness of this showing to rebut the combination of Kross and Brink et al.

Third, the Examiner's attention is directed to the following additional remarks.

U.S. Patent No. 5,618,841 (Kross) discloses a composition for improving the anti-microbial activity of mammalian iodophor teat dips. It is not a surgical scrub as recited in amended claim 54.

The composition of Kross includes an iodophor and a specific organic acid buffer (column 2, lines 43-55). Although Kross mentions that, theoretically, concentrations of the organic acid buffer of from about 0.05% to 5.0% are "desirable" (column 5, lines 29-30), such high amounts of buffer are never used in Kross. And, if such amounts are "desirable," then it is logical to assume that Kross also teaches that amounts outside this range would be "undesirable." For certain of Applicants' claims, the only point of overlap is the edge value of 5 wt-%, although

claim 1 now recites an amount in excess of 5 wt-%, thereby eliminating any overlap. Furthermore, claims 55 and 56 recite an amount of at least about 6 wt-% and an amount of at least about 7 wt-%, respectively.

Surprisingly, Applicants have found that the presently claimed compositions comprising a hydroxycarboxylic acid buffer in such high amounts (of at least about 5 wt-%, particularly in excess of 5 wt-%, more particularly in an amount of at least about 6 wt-%, and even more particularly in an amount of at least about 7 wt-%) in combination with an iodophor and a substantive film forming polymer are substantially nonirritating to tissue and provide a surprising level of rapid microbial kill. That is, the fact that the level of rapid microbial kill increases significantly with the concentrations of the hydroxycarboxylic acid in the compositions of the present invention (i.e., in combination with the iodophor and film-forming polymer, see page 13, lines 23-27 of Applicants' specification) is surprising because the compositions without an antimicrobial agent (e.g., without an iodophor), but with a hydroxycarboxylic acid and film-forming polymer are relatively inactive when used as an antiseptic (see page 10, lines 6-8 of Applicants' specification). Thus, contrary to what the Examiner alleges at page 8 of the Office Action, one of skill in the art would not be motivated to use higher amounts of acids (in spite of their ability to irritate) because the higher amounts of acids in combination with a film-forming polymer do not provide antimicrobial activity when used as an antiseptic (without an antimicrobial agent such as an iodophor being present).

The Examiner used Richter et al. for teaching methods of preventing irritancy of high levels of alpha-hydroxy acids "by buffering to an appropriate pH or the use of emollients or humectants" (page 7 of the Office Action). It is respectfully submitted that the teachings of Richter et al. are not as broadly applicable as suggested by the Examiner. Richter et al. teach that "[a]cidulants are necessary ingredients within the mastitis control treatments of the invention to maintain the appropriate pH for dissociation of the chlorite/chlorine dioxide release agent and to prevent dissociation of antimicrobial agents such as heptanoic, octanoic, nonanoic, decanoic, and undecanoic carboxylic acids employed as non-fugitive antimicrobial agents" (column 9, lines 36-

41). Thus, Richter et al. teach that when chlorite/chlorine dioxide release agents and carboxylic acids (all of which listed at column 9, lines 36-41 are fatty acids) are included in a composition, then it is desirable to include an acidulant such as citric acid, lactic acid, acetic acid, etc. Since none of the cited documents used in combination with Richter et al. (nor Applicants' claimed compositions) include both types of components, there would be no motivation to combine their teachings with the teachings of Richter et al.

Moreover, high concentrations of hydroxycarboxylic acid buffers would be expected to contribute to poor PSA-coated product adhesion and significantly reduced substantivity, since hydrophilic compounds facilitate moisture build-up from transpiration and perspiration in combination with external fluid exposure, resulting in premature adhesion failure. See, Applicants' specification at page 15, lines 16-26. This is further supported by Richter et al. at column 10, lines 27-30, who state "alpha-hydroxycarboxylic acids absorb moisture from the atmosphere and therefore, when applied topically, increase moisture content and plasticity of the stratum corneum." Thus, one of skill in the art would have been directed away from using alpha-hydroxycarboxylic acids in compositions that are to be used on skin to which a PSA-coated product is to adhere. The Examiner's attention is directed to claims 37 and 41, which recite that the composition has good PSA-coated product adhesion. This is particularly important when the composition is a surgical scrub, because surgical drape must adhere well to the skin of a patient after it has been treated with the surgical scrub, not only for convenience of the surgeon but for safety and health of the patient.

At page 8 of the Office Action, the Examiner stated that "the claims claim hydroxycarboxylic in general, as such, the alleged evidence does not appear commensurate with the scope of the claims. In any case, Richter et al. recognize that acids have an effect on the polymer film and that adjustments can be made to account for the hydrophilic components (Richter et al., Column 11, lines 64-68, Column 12, lines 1-35)." Applicants do not understand what the Examiner means by this. Richter et al. teach two types of acids – fatty carboxylic acids and alpha-hydroxy acids – and the "acids" referred to in columns 11 and 12 of Richter et al. are

the fatty carboxylic acids, not the alpha-hydroxy acids. Thus, it is not clear how this applies to Applicants' claimed invention.

The composition of Kross may also include certain polymeric materials (column 5, lines 42-53). These polymers are not all necessarily substantive (according to Applicants' definition) nor do they necessarily comprise hydrophilic and hydrophobic moieties. These are significant features of the class of film-forming polymers used in Applicant's invention – in particular, claim 39 recites that the film-forming polymer includes both hydrophilic and hydrophobic groups. Also, the Examiner's attention is directed to claim 58, which now recites that the film-forming polymer is cationic, whereas Kross does not disclose any cationic polymers.

Even if there are substantive film-forming polymers, or film-forming polymers that comprise hydrophilic and hydrophobic moieties, or cationic film-forming polymers disclosed in Kross, there is no teaching or suggestion in Kross that such polymers could be selected and combined with the other components in the recited amounts in Applicants' claims to form an antiseptic composition, absent the impermissible use of hindsight reconstruction.

At page 5 of the Office Action, the Examiner stated that "Applicant argues that the polymer in Kross are *[sic]* not necessarily substantive. However, Applicant has not provide *[sic]* any evidence of the same. The arguments of counsel cannot take the place of evidence in the record." The Examiner further stated that Brink et al. disclose the advantages of choosing a polymer which provides substantitivity. While it is true that Brink et al. disclose the advantages of choosing a substantive polymer, according to Richter et al. at column 4, lines 48-53, cellulosic polymers (which are one of the types of polymers suggested as useful by Kross at column 5, lines 47-48) "seldom perform the dual-function role of providing a tenacious barrier, being too readily removed because of its water-sensitivity." Thus, at least the cellulosic polymers disclosed as useful by Kross are not substantive.

However, even if it could be argued that both Brink et al. and Kross suggest the desirability of a substantive polymer, Applicants have presented arguments and evidence as to why one would not combine Kross and Brink et al. First, there is no teaching or suggestion of a

composition with the high amount of hydroxycarboxylic acid buffer, as recited in Applicants' claims. Second, the compositions of Brink et al. are dispersions which are salt intolerant and unstable. Referring to the Declaration of Matthew T. Scholz it is very clear that one would not use a composition of Brink et al. and add a buffer of the type and level described in Kross. If one did, the composition would be highly unstable and form a coagulated mass, as shown in the Declaration of Matthew T. Scholz.

The Examiner appears to reject this declaration (although the experiment was discussed with the Examiner prior to carrying it out) by his statement at page 9 of the Office Action that the "Examiner notes that instead of just adding additional acid, the experiments add both acid and sodium phosphate."

The rationale of the experiment is as follows. Example 27 of Brink et al. was used as a starting point (after previous discussion with the Examiner). As was done in Example 27, the disodium phosphate was added to adjust the pH of the buffer to 5-7 in order to be within the preferred range of Brink et al. (see Col. 8 line 59). The buffer was of a type to reflect both the Kross and Brink et al. inventions and at a level to reflect the Kross invention (Paragraph 4 of Declaration of Matthew T. Scholz: Example with 2% lactic acid buffer). The concentration was increased further to reflect Applicants' invention (Paragraph 5 in Declaration of Matthew T. Scholz: Example with 5% lactic acid buffer) and arguably Kross (even though a fair reading of Kross is that he never intended to use more than 2% acid and that 5% was an extreme upper end). The lactic acid was used in place of the citric acid buffer of Example 27 since lactic acid was the acid used by Kross in the highest amount in the Examples of Kross. The resultant composition that one of skill in the art would be motivated to prepare using the teachings of Kross and Brink et al. was highly unstable and formed a coagulated mass.

The Examiner alleged, at page 9 of the Office Action, that such instability "due to the addition of buffering compounds is recognized in the art and methods of preventing the same are disclosed" (referencing Talwalker et al. for teaching that "providing sufficient amount of carrier, such as a non-ionic surfactant, will stabilize the iodophore," page 4 of Office Action) and "[a]s

such, one of ordinary skill in the art would be able to adjust the composition in Brink et al. to account for any instability which may be caused by addition of a buffer in the amounts desired." Applicants respectfully disagree. There would be no motivation to use the teaching of Talwalker et al. with Brink et al. and Kross. Again, one must look at the documents as a whole and at the invention as a whole.

There are many deficiencies in Talwalker et al. that would prevent one of skill in the art from considering the teachings of Talwalker et al. as a relevant solution to the instability problem of the composition suggested by the combination of Brink et al. and Kross. First, Brink et al. is a dispersion and Talwalker et al. is a solution of the iodophor. See, e.g., column 5, lines 23-38, where Talwalker et al. teach away from forming a two-phase composition. Furthermore, Talwalker et al. use at least 3x the highest allowed amount of surfactant as that used in Brink et al. (see, e.g., Brink et al. column 8, lines 48-51). Furthermore, the compositions of Talwalker et al. that are actually used are diluted such that the available iodine concentration in the "use concentration" is less than 0.25 wt-% and the hydroxycarboxylic acid is less than 5 wt-%. See, e.g., column 6, lines 1-3, where Talkwalker et al. disclose that the compositions are "diluted to a total of between substantially 50-800 parts water to 1 part iodine-fatty acid(s) active agent intermediate." Thus, one would not be motivated to combine Talwalker et al. with Brink et al. and Kross.

The Examiner's attention is directed to the fact that Applicants' claim 42 recites that the composition is a "use concentration," which refers to a composition, with the components in the amounts recited, that is applied to the skin (page 7, lines 10-11 of Applicants' specification).

Also, with respect to claim 43, which recites that the composition has a Brookfield viscosity of less than 100 cps, the viscosity of Kross is 200 to 3000 cps, as recognized by the Examiner. There is no teaching or suggestion in Kross that such a low viscosity composition could be useful.

Again, with respect to claim 29, for example, the Examiner indicated that Kross discloses surfactants. Although the Examples all refer to IGEPAL CO-720, which is nonylphenol

ethoxylate with 12 moles of ethylene oxide (also referred to as nonylphenoxy polyoxy-ethanol, N=12), this polyether glycol forms an iodophor with iodine (see column 3, lines 28-32). That is, any IGEPAL CO-720 added would complex with the iodine. There is no teaching or suggestion of a separate surfactant in the compositions of Kross.

The rejection is also based on Beach. The Examiner stated, at page 9 of the Office Action, that Beach was cited for disclosing that "amphoteric surfactants are suitable for use in preparing iodophores." While this is true, Beach does not provide that which is missing from the combination of Kross and Brink et al. and Richter et al. and Talwalker et al. In fact, there is no teaching or suggestion of compositions that include hydroxycarboxylic acids in Beach. Thus, there is no motivation to combine this document with the four other documents.

It is respectfully submitted that there is no teaching or suggestion in the prior art of Applicants' invention. For example, there is no teaching or suggestion of how to provide antiseptics having increased speed of bactericidal activity on skin without substantial irritation while still allowing adhesion of PSA-coated products and good substantivity. There is no indication to be found in the combination of Kross, Brink et al., Beach, Talwalker et al., and Richter et al. that this problem can be solved by providing one of the antiseptic compositions of the present invention that contain, among other components, a hydroxycarboxylic acid buffer in an amount of at least about 5 wt-% (and particularly in excess of 5 wt-%), absent the impermissible use of hindsight reasoning.

## Summary

It is respectfully submitted that the pending claims 1-43 and 54-63 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of June, 2005, at 5:45pm (Central Time).

By: Sue Dombroske
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